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| **TO** | : | Commissioner for Patents<br>Mail Stop: Appeal Brief-Patents |
| **FROM** | : | Oleg F. Kaplun, Esq. of Fay Kaplun & Marcin, LLP |
| **DATE** | : | April 23, 2008 |
| **SUBJECT** | : | US Patent Appln. Serial No. 09/864,488<br>for *Anti-Clotting Methods and Apparatus for Indwelling Catheter Tubes*<br>Our Ref.: 10123/03203 |

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Attorney Docket No. 10123/03203 (01-535US03)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**



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| Inventor(s) | : | Wise et al. |
| Serial No. | : | 09/864,488 |
| Filing Date | : | May 24, 2001 |
| For | : | Anti-Clotting Methods and Apparatus for Indwelling Catheter Tubes |
| Group Art Unit: | : | 3763 |
| Confirmation No. | : | 3552 |
| Examiner | : | Phillip A. Gray |

04/24/2008 PCHOMP 00000041 09864488
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By: Oleg F. Kaplun, (Reg. No. 45,559) Date: April 23 2008

**TRANSMITTAL**

In support to the Notice of Appeal filed January 25, 2008 and the Advisory Action dated January 7, 2008, transmitted herewith please find an Appeal Brief for filing in the above-identified application. Applicants hereby request a one (1) month extension. Please charge the Credit Card of **Fay Kaplun & Marcin, LLP** in the amount of $630.00 (PTO-Form 2038 is enclosed). The Commissioner is hereby authorized to charge the **Deposit Account of Fay Kaplun & Marcin, LLP NO. 50-1492** for any additional required fees. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: April 23, 2008

By: _____
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Attorney Docket No. 10123/03203 (01-535US03)

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Respectfully submitted,

Dated: April 23, 2008

By: _____
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PATENT
Attorney Docket No.: 10123 - 03203

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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|---|---|
| In re Application of: **Wise et al.** | |
| Serial No.: 09/864,488 | Group Art Unit: 3767 |
| Filed: May 24, 2001 | Examiner: Phillip A. Gray |
| For: ANTI-CLOTTING METHODS AND APPARATUS FOR INDWELLING CATHETER TUBES | **Board of Patent Appeals and Interferences** |

Mail Stop: Appeal Brief - Patents
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## APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed on January 25, 2008, and pursuant to 37 C.F.R. § 41.37, Appellants present an appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 56 and 59 - 81 in the Final Office Action dated October 9, 2007 as clarified in the Advisory Action dated January 7, 2008. The appealed claims are set forth in the attached Claims Appendix.

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1. Real Party in Interest

This application is assigned to Boston Scientific Scimed, Inc., the real party in interest.

2. Related Appeals and Interferences

An Appeal Brief was filed on August 22, 2006. Prosecution of the present application was subsequently reopened and a Non-Final Office Action issued on March 9, 2007.

3. Status of the Claims

Claims 56 and 59 - 81 have been rejected in the Final Office Action and are the subject of the present appeal. Claims 1 - 54 have been canceled. Claims 55, 57, 58, 67 and 73 have been withdrawn.

4. Status of Amendments

All submitted amendments have been entered.

5. Summary of Claimed Subject Matter

The present invention, as recited in independent claim 56, describes a system for establishing intermittent fluid communication with the bloodstream comprising a catheter 26 including first and second lumens 20, 24 extending therethrough from a proximal end of the catheter 26 to a distal end 67 which, when in an operative position, resides within a blood vessel 22. (*See* Specification, ¶ [0029], [0033]; Fig. 3). The system of claim 56 further includes a first

sealing balloon 76 positionable within a distal end of the first lumen 20, so that, when inflated, the first balloon 76 seals the distal end 67 of the first lumen to prevent blood flow thereinto, and a deflation mechanism 70 for deflating the first balloon 76 to reopen the first lumen 20 to blood flow thereinto while the distal end 67 of the catheter 26 remains within the blood vessel 22. (*Id.* at ¶ [0033] – [0037]; Figs. 3 - 5, 7)

Claim 59 is directed to a method of sealing a catheter 26 indwelling within a vessel 22, comprising the acts of advancing a first deflated balloon 76 along a first lumen 24 of the catheter 26 to a position at least partially radially within a distal end 67 thereof. (*Id.* at ¶ [0029], [0033] – [0038]; Figs. 3 - 5, 7]. Claim 59 recited a further step of inflating the first balloon 76 to seal the first lumen 24 at the distal end thereof to prevent fluid from entering the distal end of the first lumen 24. (*Id.*). Claim 59 further teaches a step of purging the first lumen 24. (*Id.*).

Claim 64 is directed to a method of sealing a catheter 26 indwelling within a vessel 22 comprising the acts of terminating flow along a hollow interior passageway 66 of the catheter 26. (*Id.* at ¶ [0029], [0033] – [0038]; Figs. 3 - 5, 7). Claim 64 further recites inflating a balloon 76 to seal the hollow interior passageway 66 at a distal end 67 of the catheter 26 to prevent blood in the vessel 22 from entering the hollow interior passageway 66. (*Id.*). Claim 64 is further directed to deflating the previously inflated balloon 76 to unseal the hollow interior passageway 66 when flow through the hollow interior passageway 66 of the catheter 26 is desired and withdrawing the balloon 76 from the catheter 26 after the deflating act. (*Id.*)

Claim 65 is directed to a system for establishing intermittent fluid communication with the bloodstream comprising a catheter 26 including a lumen 24 extending therethrough from a proximal end of the catheter to a distal end 67 thereof, and, when in an operative position, the distal end 67 of the catheter 26 resides within a blood vessel 22 of a patient. (*Id.* at ¶ [0029], [0033] – [0038]; Figs. 3 - 5, 7). The system of claim 65 further includes a balloon 76 which,

when inflated, physically contacts and seals the distal end 67 of the lumen to prevent blood flow thereinto, and a deflation mechanism 70 for deflating the balloon 76 to reopen the lumen 24 to blood flow thereinto while the distal end 67 of the catheter 26 remains within the blood vessel 22. (*Id.*)

Claim 70 is directed to a system for establishing intermittent fluid communication with the bloodstream comprising first and second non-concentric catheters 20, 24 each of the first and second catheters 20, 24 including a lumen extending therethrough between proximal and distal ends thereof, and, when in an operative position, the distal ends of the first and second catheters 20, 24 reside within a blood vessel 22 of a patient. (*Id.* at ¶ [0029], [0034] – [0037]; Figs. 3 - 5, 7 - 8). The system further includes first and second balloons 76 positionable within distal ends of the first and second catheters 20, 24, respectively, so that, when inflated, the first and second balloons 76 seals the respective distal ends of the lumens of the first and second catheters 20, 24 to prevent blood flow thereinto, and a deflation mechanism 70 for deflating the balloon 76 to reopen the lumen to blood flow thereinto while the distal end of the catheter 20, 24 remains within the blood vessel 22. (*Id.*)

Claim 80 is directed to a method of treating a bodily fluid comprising the steps of inserting a distal end of a catheter 26 into a body lumen 22 including the bodily fluid and establishing fluid communication with the body lumen 22 via a first lumen of the catheter 26 to initiate a first treatment session to treat the bodily fluid. (*Id.* at ¶ [0007], Fig. 3). Claim 80 further teaches a step of sealing the first lumen to discontinue fluid communication with the bodily fluid by advancing a first deflated balloon 76 along the first lumen to a position at least partially radially within a distal end 37 thereof. (*Id.* at ¶ [0007], [0034] - [0038]; Figs. 3 - 8). Claim 80 goes on to recite the step of inflating the first balloon 76 to seal the first lumen at the distal end 67 thereof and reestablishing fluid communication with the bodily fluid by deflating

the first balloon 76 to initiate a second treatment session. (*Id.*)

6. Grounds of Rejection to be Reviewed on Appeal

I. Whether claim 56 is unpatentable under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter of the invention

II. Whether claims 56, 59 - 66, 68 - 69 and 80 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Horzewski (U.S. Pat. No. 4,771,777)

III. Whether claims 56, 59 - 66, 68 - 69 and 80 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Wijay (U.S. Pat. No. 5,158,540)

IV. Whether claims 56, 59 - 66, 68 - 69 and 80 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Calderon (U.S. Pat. No. 4,867,742)

V. Whether claims 56, 59 - 66, 68 - 69 and 80 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Cannnon (U.S. Pat. No. 5,403,274)

VI. Whether claims 59 - 64 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Wijay or alternatively, under 35 U.S.C. § 103(a) as obvious over Wijay in view of Burns (U.S. Pat. No. 5,176,698)

VII. Whether claims 70 - 72, 74 - 79 and 81 are unpatentable under 35 U.S.C. § 103(a) as obvious over Wijay or alternatively, over Horzewski or alternatively, over Calderon or alternatively, over Cannon

7. Argument

I. The Rejection of Claim 56 Under 35 U.S.C. § 112, Second Paragraph, Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, the Examiner rejected claim 56 under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the invention. (*See* 10/9/07 Office Action, p. 4). Specifically, the Examiner stated that it was unclear how the catheter of claim 56 includes first and second lumens extending therethrough when, from the drawings, it appears that the catheter has one distal end and two separate proximal ends. (Id.).

B. The Limitations Recited in Claim 56 are Shown in the Drawings

Claim 56 recites a system for establishing intermittent fluid communication with a patient's bloodstream comprising "a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end thereof, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient." It is noted that although the embodiment of Fig. 7 depicts a dual lumen catheter 26 comprising a Y-adapter, there is no limitation in the claims limiting the catheter to such a construction. Thus, the "proximal end of the catheter" recited in claim 56 clearly refers to that part of the catheter which includes the proximal ends of the first and second

lumens 20, 24 as made clear in the claims. Specifically, it is respectfully submitted that the drawings in no way impact the meaning or clarity of the claim itself, irrespective of whether such a proximal end comprises one piece, two pieces or one hundred pieces in the drawings. It is further respectfully submitted that it is improper to read such a limitation into the claim. It is therefore respectfully submitted that a proximal end of the catheter of claim 56 is shown in the drawings and that claim 56 fully complies with 35 U.S.C. § 112, second paragraph. It is therefore respectfully requested that this rejection be withdrawn.

## II. The Rejection of Claims 56, 59 - 66, 68 - 69 and 80 as Anticipated by Wijay Should be Reversed

### A. The Examiner's Rejection

In the Final Office Action, the Examiner rejected claims 56, 59 - 66, 68 - 69 and 80 under 35 U.S.C. 102(b) as anticipated by Wijay. (*See* 10/9/07 Office Action, pp. 2 - 6). In support of the rejection, the Examiner stated that Wijay discloses and is fully capable of being a system for establishing intermittent communication within the bloodstream. (*Id.*) The Examiner further adds that the elements taught by Wijay are fully capable of satisfying all structural, operational, functional and spatial limitations of the claims. (*Id.*)

Claim 56 recites a system for establishing intermittent fluid communication with a patient's bloodstream comprising "a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end thereof, wherein, when in

an operative position, the distal end of the catheter resides within a blood vessel of a patient" in combination with "*a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*" and "*a deflation mechanism for deflating the first balloon to reopen the first lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel.*"

B. Wijay does not Disclose a First Sealing Balloon Positionable Within a Distal End of the First Lumen to Seal the Distal End of the First Lumen as Recited in Claim 56

The Examiner has previously indicated that the limitation of a first balloon positionable "so that, when inflated, the first balloon seals the distal end of the first lumen to prevent flow therein," as recited in claim 56 is read as a functional/operational limitation. (*See* 10/9/07 Office Action, p. 2). However, it is respectfully submitted that the aforementioned limitation does not merely define the function of the first sealing balloon, but also necessarily limits the structure thereof. Specifically, the limitation noted above limits the claimed element to those balloons having the physical characteristics necessary to carry out this function (i.e., shape, size, location relative to features of the device, etc.) and make clear that this limitation is met only by a balloon constructed and positioned with respect to the other device elements in such a manner that, when inflated, the distal end of the first lumen is sealed. It is further noted that, reading this limitation out of the claim allows the claim to encompass very different structures -- i.e., those including balloons which, when inflated, are unable to seal the distal end of a lumen of

the device either through deficiencies in size, positioning, etc. and which are thus unable to prevent blood flow into the lumen. Accordingly, it is submitted that the language "*so that, when inflated, the first balloon seals the distal end of the first lumen to prevent flow therein*," as recited in claim 56, is a structural limitation which clearly defines physical characteristics of the balloon and its relation to the rest of the claimed combination.

It is further noted that Wijay does not teach or suggest "a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto", as recited in claim 56. Specifically, Wijay shows a balloon 16 in an annular passage 30. However, it is noted that the balloon 16 is neither located nor locatable at "a distal end" of this annular passage and cannot, therefore, prevent blood flow thereinto, as recited in claim 56. Rather, the balloon 16 is positioned along a length of the annular passage 30 spaced from a distal end thereof to seal off the annular passage 30 for distal hemoperfusion. (*See* Wijay, col. 4, ll. 16 - 19; Fig. 1). It is noted that the positioning of the balloon 16 in the Wijay device is selected to allow blood and/or other fluids to enter proximal portions as well as the distal end of the annular passage 30 and is designed only to prevent blood from flowing distally past the balloon -- i.e., preventing flow through the passage 30 past the balloon 16.. That is, when blood is pumped into the annular space 30, the balloon 16 prevents this blood from flowing out of the annular space 30 into the portion of the artery proximal to the balloon 17. Rather, this blood is forced into the lumen 26 via holes 15 so that it may enter the artery distal to the balloon 17, maintaining blood flow through the artery. (*See* Wijay, col. 4, ll. 19 - 26). Thus, the balloon 16 is positioned immediately distal to the openings 15 and the balloon 16 is not designed to prevent blood from flowing into the distal portion of the annular space 30, nor is the balloon 16 suitable for

this purpose. Nor does Wijay or the Examiner provide any reason why such a position would be desirable or even acceptable in such a device. It is therefore noted that Wijay does not teach or suggest "*a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*", as recited in claim 56.

Furthermore, it is noted that the second sealing balloon 17 of the Wijay device also does not cure the deficiencies of the first balloon 16. Specifically, it is noted that the balloon 17 is not "positionable within a distal end of the first lumen," as recited in claim 56. Rather, the device is operable only when the balloon 17 is inflated in the artery at the stenosis. (*See* Wijay, col. 4, ll. 13 - 16). It is therefore noted that Wijay neither shows nor suggests a catheter including any structure for preventing blood flow into the distal end of a lumen thereof, as recited in claim 56.

Still further, it is respectfully submitted that employing a sealing balloon at a distal end of the annular space of the Wijay device to prevent blood flow thereinto, as recited in claim 56, would be detrimental to the functioning of the Wijay device. Specifically, Wijay is directed to maintaining fluid communication between the catheter and the lumen of the patient while changing the routes of this communication. (*See* Wijay, col. 2, ll. 55 - 59). Modifying the device of Wijay to prevent flow therebetween when a first balloon is inflated would therefore prove to be detrimental thereto. It is noted that is a proposed modification renders the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. (*See* In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)). It is therefore respectfully submitted that the proposed modification of the Wijay device is an impermissible hindsight reconstruction of the invention and is insufficient to

support a rejection under either of §§102 and 103.

For these reasons, it is respectfully submitted that Wijay neither teaches nor suggests "*a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*," as recited in claim 56 and that claim 56 is allowable for at least this reason.

Claim 59 recites limitations substantially similar to those of claim 56 including "inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen." Thus, it is respectfully submitted that claim 59 is allowable for at least the same reasons as claim 56. Because claim 60 - 63 depend from, and therefore, include all of the limitations of claim 59, it is respectfully submitted that these claims are also allowable.

Claim 64 recites limitations substantially similar to those of claim 56 including "inflating a balloon to seal the hollow interior passageway at a distal end of the catheter to prevent blood in the vessel from entering the hollow interior passageway." Thus, it is respectfully submitted that claim 64 is allowable for at least the same reasons as claim 56.

Claim 65 recites limitations substantially similar to those of claim 56 including "a balloon which, when inflated, physically contacts and seals the distal end of the lumen to prevent blood flow thereinto." Thus, it is respectfully submitted that claim 65 is allowable for at least the same reasons as claim 56. Because claims 66 and 68 - 69 depend from, and, therefore include all of the limitations of claim 65, it is respectfully submitted that these claims are also allowable.

Claim 80 recites limitations substantially similar to those of claim 56 including "sealing the first lumen to discontinue fluid communication with the bodily fluid by:

advancing a first deflated balloon along the first lumen to position at least partially radially within a distal end thereof; and inflating the first balloon to seal the first lumen at the distal end thereof." Thus, it is respectfully submitted that claim 80 is allowable for at least the same reasons as claim 56.

## III. The Rejection of Claims 56, 59 - 66, 68 - 69 and 80 as Anticipated by Horzewski Should be Reversed

### A. The Examiner's Rejection

In the Final Office Action, the Examiner rejected claims 56, 59 - 66, 68 - 69 and 80 under 35 U.S.C. 102(b) as anticipated by Horzewski. (*See* 10/9/07 Office Action, p. 6). In support of the rejection, the Examiner has stated that Fig. 9 of Horzewski teaches the limitations of claims 56, 59 - 66, 68 - 69 and 80. (*Id.*)

### B. The Cited Reference does not Disclose a First Sealing Balloon Positionable Within a Distal End of the First Lumen, as Recited in Claim 56

Horzewski purports to show a perfusion-type dilation apparatus for regulating the flow of blood pumped into a stenosis. It is noted that Horzewski does not teach or suggest "a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end thereof, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient" in combination with "a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to

prevent blood flow thereinto" and "a deflation mechanism for deflating the first balloon to reopen the first lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel," as recited in claim 56.

The Examiner references tubular member 14 and balloon 82 of the Horzewski device in support of this rejection. It is noted that the balloon 82 is situated on a distal end of the tubular member 14, which contains only the lumen 18. (*See* Horzewski, col. 2, ll. 28 - 30). Claim 56, on the other hand, recites the employment of "a catheter including *first and second* lumens extending therethrough." Horzewski teaches *only one lumen* extending therethrough from a proximal to a distal end. It is submitted that the tubular membrane 77, which contains at least one lumen does not share proximal and distal ends with the tubular member 14 and therefore does not teach the limitations of claim 56. (*See* Horzewski, Fig. 9). It is therefore noted that Horzewski does not teach or suggest "*a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end thereof*, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient," as recited in claim 56.

Furthermore, Horzewski teaches a balloon 82 which is situated along the tubular membrane 77 which contains a plurality of openings 92 and circumferentially placed holes 93. (*See* Horzewski, col. 5, line 65 to col. 6, line 12; Fig. 9). These openings are designed to allow blood to travel to/from the stenosis even during inflation, so as to avoid a situation where blood flow is temporarily blocked between the catheter and the stenosis. Specifically, Horzewski notes that "[b]lood therefore flows through the dilatation catheter into a region beyond the stenosis so that there is a continued supply of blood to the heart muscle during the period of inflation of the balloon." (*Horzewski*, col. 7, ll. 22 - 28). It is therefore noted that Horzewski does not teach or suggest a catheter including a balloon

sealing the distal end of a first lumen "to prevent blood flow thereinto," as recited in claim 56. Rather, Horzewski deliberately tries to overcome a situation where blood flow would be blocked by introducing the plurality of openings 92 and circumferentially placed holes 93 into the design. Additionally, it is noted that the employment of a design that "seals a distal end of the first lumen to prevent blood flow thereinto," as recited in claim 56, would be detrimental to the operation of the Horzewski device which must permit constant fluid communication between the catheter and the stenosis of the artery. (*Id.*)

Thus it is respectfully submitted that Horzewski neither teaches nor suggests "a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, *the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*" and "a deflation mechanism for deflating the first balloon *to reopen the first lumen to blood flow thereinto* while the distal end of the catheter remains within the blood vessel," as recited in claim 56 and that claim 56 is allowable.

Claim 59 recites limitations substantially similar to those of claim 56 including "inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen" and "purging the first lumen." Thus, it is respectfully submitted that claim 59 is allowable for at least the same reasons as claim 56. Because claim 60 - 63 depend from, and therefore, include all of the limitations of claim 59, it is respectfully submitted that these claims are also allowable.

Claim 64 recites limitations substantially similar to those of claim 56 including *"inflating a balloon to seal the hollow interior passageway* at a distal end of the catheter to prevent blood in the vessel from entering the hollow interior passageway" and *"deflating the previously inflated balloon to unseal the hollow interior passageway* when

flow through the hollow interior passageway is desired." Thus, it is respectfully submitted that claim 64 is allowable for at least the same reasons as claim 56.

Claim 65 recites limitations substantially similar to those of claim 56 including "a balloon which, when inflated, physically contacts and seals the distal end of the lumen to prevent blood flow thereinto" and "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel." Thus, it is respectfully submitted that claim 65 is allowable for at least the same reasons as claim 56. Because claims 66 and 68 - 69 depend from, and, therefore include all of the limitations of claim 65, it is respectfully submitted that these claims are also allowable.

Claim 80 recites limitations substantially similar to those of claim 56 including "sealing the first lumen to discontinue fluid communication with the bodily fluid by: advancing a first deflated balloon along the first lumen to position at least partially radially within a distal end thereof; and inflating the first balloon to seal the first lumen at the distal end thereof" and "reestablishing fluid communication with the bodily fluid by deflating the first balloon to initiate a second treatment session." Thus, it is respectfully submitted that claim 80 is allowable for at least the same reasons as claim 56.

## IV. The Rejection of Claims 56, 59 - 66, 68 - 69 and 80 as Anticipated by Calderon Should be Reversed

### A. The Examiner's Rejection

In the Final Office Action, the Examiner rejected claims 56, 59 - 66, 68 - 69 and 80 under 35 U.S.C. 102(b) as anticipated by Calderon. (*See* Final Office Action, 10/9/07,

p. 6).

B. The Cited Reference does not Disclose a First Sealing Balloon as Recited in Claim 56

The Examiner has analogized the balloon 56 of the Calderon device to the first sealing balloon disclosed in claim 56. However, it is noted that the balloon 56 of the Calderon device is positioned along an outer circumference of the distal end of the suction lumen 52 and in no way controls the flow of fluids into an internal lumen of the device. (*See* Calderon, Figs. 2, 3). Specifically, the balloon 56 is "inflatable in the patient's vein via a port *to seal the vein*, blocking the flow of infused fluids from the injection lumen 18 to the remainder of the patient's body." (*Calderon*, col. 6, ll. 47 - 51). That is, the balloon of Calderon controls the flow of fluids injected into a patient by preventing these fluids from passing around the outside of the catheter to undesired parts of the body and does not "seal the distal end of the first lumen to prevent blood flow thereinto," as recited in claim 56. The balloon 52 is external to the catheter lumen and only seals against the periphery of the vein while leaving the lumen itself open to fluid flow. This lumen must remain open for the device to function. For the same reasons, it is also submitted that Calderon does not teach a device whereby the balloon may be deflated "to reopen the first lumen to blood flow thereinto," as recited in claim 56.

It is respectfully submitted that Calderon neither teaches nor suggests "a catheter including first and second lumens *extending therethrough from a proximal end of the catheter to a distal end thereof*, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient" in combination with "*a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*"

and "a deflation mechanism for *deflating the first balloon to reopen the first lumen to blood flow thereinto* while the distal end of the catheter remains within the blood vessel," as recited in claim 56 and that claim 56 is allowable.

Claim 59 recites limitations substantially similar to those of claim 56 including "inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen" and "purging the first lumen." Thus, it is respectfully submitted that claim 59 is allowable for at least the same reasons as claim 56. Because claim 60 - 63 depend from, and therefore, include all of the limitations of claim 59, it is respectfully submitted that these claims are also allowable.

Claim 64 recites limitations substantially similar to those of claim 56 including *"inflating a balloon to seal the hollow interior passageway* at a distal end of the catheter *to prevent blood in the vessel from entering the hollow interior passageway*" and *"deflating the previously inflated balloon to unseal the hollow interior passageway* when flow through the hollow interior passageway is desired." Thus, it is respectfully submitted that claim 64 is allowable for at least the same reasons as claim 56.

Claim 65 recites limitations substantially similar to those of claim 56 including "a balloon which, when inflated, physically contacts and seals the distal end of the lumen *to prevent blood flow thereinto*" and "a deflation mechanism for *deflating the balloon to reopen the lumen to blood flow thereinto* while the distal end of the catheter remains within the blood vessel." Thus, it is respectfully submitted that claim 65 is allowable for at least the same reasons as claim 56. Because claims 66 and 68 - 69 depend from, and, therefore include all of the limitations of claim 65, it is respectfully submitted that these claims are also allowable.

Claim 80 recites limitations substantially similar to those of claim 56 including

"*sealing the first lumen to discontinue fluid communication with the bodily fluid* by: advancing a first deflated balloon along the first lumen to position at least partially radially within a distal end thereof; and *inflating the first balloon to seal the first lumen at the distal end thereof*" and "*reestablishing fluid communication with the bodily fluid by deflating the first balloon* to initiate a second treatment session." Thus, it is respectfully submitted that claim 80 is allowable for at least the same reasons as claim 56.

## V. The Rejection of Claims 56, 59 - 66, 68 - 69 and 80 as Anticipated by Cannon Should be Reversed

### A. The Examiner's Rejection

In the Final Office Action, the Examiner rejected claims 56, 59 - 66, 68 - 69 and 80 under 35 U.S.C. § 102(b) as anticipated by Calderon. (*See* Final Office Action, 10/9/07, p. 7).

### B. The Cited Reference does not Disclose a First Sealing Balloon as Recited in Claim 56

Cannon purports to describe a catheter for pressure equalization of fluids traveling between the catheter and a blood vessel. (*See* Cannon, col. 2, line 64 to col. 3, line 1). Specifically, the Cannon device contains a balloon 44 located along a distal end of a guide catheter 12, distal to a port 32 and at least one opening 48 located along the guide catheter 12. (*See* Cannon, col. 3, ll. 7 - 11). Cannon states that the "guide catheter 12 may have more than one opening to enable fluid communication between the blood vessel BB and the guide lumen 18." (*Cannon*, col. 5, ll. 11 - 14). In light of the above, it is

noted that the balloon 44 of the Cannon device does not "seal the distal end of the first lumen to prevent blood flow thereinto," as recited in claim 56. Rather, the balloon 44 equalizes pressure inside the catheter and within the vessel while permitting fluid flow between the vessel and the catheter lumen, so that a physician may apply a regulated amount of pressure to the blood vessel being infused. (*See* Cannon, col. 6, ll. 3 - 10). The port 32 and at least one opening 48 of the Cannon device ensure that, even with the balloon 44 inflated, the injection port is always in fluid communication with the blood vessel. Thus, it is respectfully submitted that, not only does Cannon show no sealing of its catheter lumen as claimed, in fact it teaches away from such a modification as a sealed end would prevent the performance of its intended function -- i.e., applying pressure to the plunger 62 to force fluid into the guide lumen 18 to initiate flow from the blood vessel, into the opening 48, into the port 32m through the first balloon lumen, past the inflated balloon 44 and the inflated distal balloon 22, and out the opening 34 at the distal end 24 of the balloon catheter 20. (*See* Cannon, col. 6, ll. 3 - 10).

It is respectfully submitted therefore that Cannon does not teach or suggest "*a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end thereof*, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient" in combination with "a first sealing balloon positionable within a distal end of the first lumen, so that, *when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto*" and "a deflation mechanism for *deflating the first balloon to reopen the first lumen to blood flow thereinto* while the distal end of the catheter remains within the blood vessel," as recited in claim 56 and that claim 56 is allowable.

Claim 59 recites limitations substantially similar to those of claim 56 including

"inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen" and "purging the first lumen." Thus, it is respectfully submitted that claim 59 is allowable for at least the same reasons as claim 56. Because claim 60 - 63 depend from, and therefore, include all of the limitations of claim 59, it is respectfully submitted that these claims are also allowable.

Claim 64 recites limitations substantially similar to those of claim 56 including *"inflating a balloon to seal the hollow interior passageway* at a distal end of the catheter *to prevent blood in the vessel from entering the hollow interior passageway*" and *"deflating the previously inflated balloon to unseal the hollow interior passageway* when flow through the hollow interior passageway is desired." Thus, it is respectfully submitted that claim 64 is allowable for at least the same reasons as claim 56.

Claim 65 recites limitations substantially similar to those of claim 56 including "a balloon which, when inflated, physically contacts and seals the distal end of the lumen *to prevent blood flow thereinto*" and "a deflation mechanism for *deflating the balloon to reopen the lumen to blood flow thereinto* while the distal end of the catheter remains within the blood vessel." Thus, it is respectfully submitted that claim 65 is allowable for at least the same reasons as claim 56. Because claims 66 and 68 - 69 depend from, and, therefore include all of the limitations of claim 65, it is respectfully submitted that these claims are also allowable.

Claim 80 recites limitations substantially similar to those of claim 56 including "*sealing the first lumen to discontinue fluid communication with the bodily fluid* by: advancing a first deflated balloon along the first lumen to position at least partially radially within a distal end thereof; and *inflating the first balloon to seal the first lumen at the distal end thereof*" and "*reestablishing fluid communication with the bodily fluid by*

*deflating the first balloon* to initiate a second treatment session." Thus, it is respectfully submitted that claim 80 is allowable for at least the same reasons as claim 56.

VI. The Rejection of Claims 59 - 64 as Anticipated by Wijay or, alternatively, as Obvious over Wijay in View of Burns Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, the Examiner rejected claims 59 - 64 under 35 U.S.C. § 102(b) as anticipated by Wijay or alternatively, under 35 U.S.C. § 103(a) as obvious over Wijay in view of Burns. (*See* Final Office Action, 10/9/07, pp. 7 - 8).

B. The Cited Reference does not Disclose a First Sealing Balloon as Recited in Claim 56

As stated above, Wijay neither discloses nor suggests "inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen," as recited in claim 59. It is respectfully submitted that Burns does not cure the deficiencies of Wijay. Specifically, the balloon 16 of Burns is disposed circumferentially around a distal end opening 47 of a shaft 14 and never seals or opens the distal end opening 47. Thus, it is respectfully submitted that Wijay and Burns taken either alone or in combination, neither show nor suggest inflating a "first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen," as recited in claim 59. Because claims 60 - 63 depend from, and, therefore include all of the limitations of claim 59, it is respectfully submitted that these claims are

also allowable.

Claim 64 recites limitations substantially similar to those of 59 including "inflating a balloon to seal the hollow interior passageway at a distal end of the catheter to prevent blood in the vessel from entering the hollow interior passageway." Therefore, at least for the reasons described above with respect to claim 59, it is respectfully submitted that claim 64 is also allowable.

## VII. The Rejections of Claims 70 - 72, 74 - 79 and 81 as Obvious Over Wijay or Alternatively, Under Horzewski or, Alternatively, Over Calderon or, Alternatively, Over Cannon Should be Reversed.

### A. The Examiner's Rejection

In the Final Office Action, the Examiner rejected claims 70 - 72, 74 - 79 and 81 under 35 U.S.C. § 103(a) as obvious over obvious over Wijay .or alternatively, under Horzewski or alternatively, under Calderon or alternatively, under Cannon . (*See* Final Office Action, 10/9/07, p. 8).

### B. The Cited Reference does not Disclose First and Second Balloons Positionable Within Distal Ends of First and Second Catheters as Recited in Claim 70

Claim 70 recites a system for establishing intermittent fluid communication with a patient's bloodstream comprising "first and second non-concentric catheters each of the first and second catheters including a lumen extending therethrough between proximal and distal ends thereof, wherein, when in an operative position, the distal ends of the first a and second catheters reside within a blood vessel of a patient" in combination with

"first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto" and "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel."

Wijay fails to teach or suggest "first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto" and "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel.". Rather, as discussed above Wijay discloses a balloon 16 in the annular passage 30, which is not located at a distal end of the lumen to prevent blood flow thereinto, as recited in claim 70. The balloon 16 is positioned along a length of the annular passage 30 to seal off the annular passage 30 for distal hemoperfusion. (*See* Wijay, col. 4, ll. 16 - 19; Fig. 1). This positioning of the balloon 16 in the Wijay device allows blood and other fluids to enter the annular passage 30. Furthermore, it is noted that the second sealing balloon 17 of the Wijay device also does not cure the deficiencies of the first balloon 16. Specifically, it is noted that the balloon 17 is not positionable within a distal end of the lumen, as noted in claim 70. Rather, the balloon 17 is situated and inflated in the stenosis. (*See* Wijay, col. 4, ll. 13 - 16). It is therefore noted that the Wijay device is not directed to a catheter that may position a sealing balloon to prevent blood flow into the catheter, as noted in claim 70.

As described above, the recitation of "first and second balloons positionable

within distal ends of the first and second catheters, respectively, so that, *when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto*" is a structural limitation of the claimed system. It is therefore respectfully submitted that Wijay neither teaches nor suggests "first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto," as recited in claim 70 and that claim 70 is allowable. Because claims 71, 72 and 74 depend from and include all of the limitations of claim 70, it is respectfully submitted that these claims are also allowable.

Claims 75 - 79 depend from, and therefore, include all the limitations of claim 59. As noted above, claim 59 is allowable over Wijay. It is therefore submitted that claims 75 - 79 are also allowable. Claim 81 depends from, and therefore includes all the limitations of claim 56, which, as noted above, is also allowable over Wijay. It is therefore submitted that claim 81 is allowable.

Horzewski also fails to teach or suggest "first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto" and "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel," as recited in claim 70.

As noted above, Horzewski teaches a balloon 82 which is situated along the tubular membrane 77 which contains a plurality of openings 92 and circumferentially placed holes 93. (*See* Horzewski, col. 5, line 65 to col. 6, line 12; Fig. 9). These

openings are designed to allow blood to travel to/from the stenosis even during inflation, to avoid even a temporary blockage of blood flow between the catheter and the stenosis. Specifically, Horzewski notes that "[b]lood therefore flows through the dilatation catheter into a region beyond the stenosis so that there is a continued supply of blood to the heart muscle during the period of inflation of the balloon." (*Horzewski*, col. 7, ll. 22 - 28). It is therefore noted that Horzewski does not teach or suggest a catheter that may "seal[s] the distal end of the first lumen to prevent blood flow thereinto," as recited in claim 56. Rather, Horzewski deliberately tries to overcome a situation where blood flow would be blocked by introducing the plurality of openings 92 and circumferentially placed holes 93 into the design.

It is therefore submitted that Horzewski fails to teach or suggest the limitations of claim 70 and that claim 70 is allowable. Because claims 71, 72 and 74 depend from and include all of the limitations of claim 70, it is respectfully submitted that these claims are also allowable.

Claims 75 - 79 depend from, and therefore, include all the limitations of claim 59. As noted above, claim 59 is allowable over Horzewski. It is therefore submitted that claims 75 - 79 are also allowable. Claim 81 depends from, and therefore includes all the limitations of claim 56, which, as noted above, is also allowable over Horzewski. It is therefore submitted that claim 81 is allowable.

Calderon also fails to teach or suggest "first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto" and "a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of

the catheter remains within the blood vessel," as recited in claim 70.

As noted above, the balloon 56 of Calderon is located along the outer circumference of the distal end of the suction lumen 52. (*See* Calderon, Figs. 2, 3). The balloon 56 is "inflatable in the patient's vein via a port to deal the vein, blocking the flow of infused fluids from the injection lumen 18 to the remainder of the patient's body." (*Calderon*, col. 6, ll. 47 - 51). It is therefore noted that the balloon of the Calderon device inflates to prevent infusion fluid from passing around the outside of the catheter to certain portions of the anatomy and does not "seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto," as recited in claim 70. Furthermore, Calderon does not teach a device whereby the balloon may be deflated "to reopen the lumen to blood flow thereinto," as recited in claim 70.

It is therefore submitted that Calderon fails to teach or suggest the limitations of claim 70 and that claim 70 is allowable. Because claims 71, 72 and 74 depend from and include all of the limitations of claim 70, it is respectfully submitted that these claims are also allowable.

Claims 75 - 79 depend from, and therefore, include all the limitations of claim 59. As noted above, claim 59 is allowable over Calderon. It is therefore submitted that claims 75 - 79 are also allowable. Claim 81 depends from, and therefore includes all the limitations of claim 56, which, as noted above, is also allowable over Calderon. It is therefore submitted that claim 81 is allowable.

Cannon also fails to teach or suggest "first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto" and "a deflation mechanism for

deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel," as recited in claim 70.

As noted above, the Cannon device contains a balloon 44 located along a distal end of a guide catheter 12, the balloon 44 being distal to a port 32 and at lease one opening 48 located along the guide catheter 12. (*See* Cannon, col. 3, ll. 7 - 11). Cannon goes on to state that the "guide catheter 12 may have more than one opening to enable fluid communication between the blood vessel BB and the guide lumen 18." (*Cannon*, col. 5, ll. 11 - 14). In light of the above, it is noted that the balloon 44 of the Cannon device is not designated to "seal the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto," as recited in claim 70. Rather, the balloon 44 is employed to equalize the pressure level inside the catheter, so that a physician may apply a regulated amount of pressure to the blood vessel being infused. (*See* Cannon, col. 6, ll. 3 - 10). The port 32 and at lease one opening 48 of the Cannon device ensure that, even with the balloon 44 inflated, the injection port is always in fluid communication with the blood vessel.

It is therefore submitted that Cannon fails to teach or suggest the limitations of claim 70 and that claim 70 is allowable. Because claims 71, 72 and 74 depend from and include all of the limitations of claim 70, it is respectfully submitted that these claims are also allowable.

Claims 75 - 79 depend from, and therefore, include all the limitations of claim 59. As noted above, claim 59 is allowable over Cannon. It is therefore submitted that claims 75 - 79 are also allowable. Claim 81 depends from, and therefore includes all the limitations of claim 56, which, as noted above, is also allowable over Cannon. It is therefore submitted that claim 81 is allowable.

9. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 102(b) and indicate that claims 1 - 27 and 30 - 36 are allowable.

Respectfully submitted,

Date: April 23 2008

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## CLAIMS APPENDIX

1 - 54. (Cancelled)

55. (Withdrawn) In combination, a catheter tube for selective flow through a hollow passageway of the catheter tube to or from a patient and a balloon selectively inflated to close and seal the hollow passageway at a distal end of the catheter tube against entry of blood when flow is not occurring through the hollow passageway;

a seal being interposed between the catheter tube and a stem within the hollow passageway at a proximal end of the catheter tube, the stem being selectively displaceable along the hollow passageway through a central opening in the seal, the seal being selectively compressed by a control to clamp against the stem to prevent stem displacement.

56. (Previously Presented) A system for establishing intermittent fluid communication with a patient's bloodstream, comprising:

a catheter including first and second lumens extending therethrough from a proximal end of the catheter to a distal end thereof, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient; and

a first sealing balloon positionable within a distal end of the first lumen, so that, when inflated, the first balloon seals the distal end of the first lumen to prevent blood flow thereinto; and

a deflation mechanism for deflating the first balloon to reopen the first lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel.

57. (Previously Presented) In combination, a catheter tube comprising a hollow unobstructed passageway for selective liquid flow therethrough to or from a patient and a balloon positionable within the unobstructed passageway and selectively inflated to close, seal and completely occlude all of the hollow passageway at a distal end of the catheter tube against entry of blood when flow is not occurring through the hollow passageway, the balloon comprising an expandable portion of a wall of the catheter tube.

58. (Previously Presented) In combination, ingress and egress catheter tubes for selective flow through a hollow passageway in each catheter tube respectively to and from the patient and a balloon associated with each catheter to accommodating selective inflation of the balloons to generally concurrently close and seal the two hollow passageways at respective distal ends of the ingress and egress catheter tubes against entry of blood from a vessel of the patient when flow is not occurring through the hollow passageways, the balloons being carried near distal ends of spaced inflation/deflation stems extending respectively within the hollow passageways for substantially the full length of the respective catheter tubes;

a seal interposed between each catheter tube and the associated stem within the hollow passageway of said catheter tube at a proximal end of said catheter tube, each stem being selectively displaceable through a central opening with the associated seal;

the seal being selectively compressed by a control to clamp against the associated stem to prevent stem displacement.

59. (Previously Presented) A method of sealing a catheter indwelling within a vessel of a patient, comprising the acts of:

advancing a first deflated balloon along a first lumen of the catheter to a position at least partially radially within a distal end thereof;

inflating the first balloon to seal the first lumen at the distal end thereof to prevent fluid from entering the distal end of the first lumen; and

purging the first lumen.

60. (Previously Presented) A method according to claim 59, wherein the first lumen is purged in a proximal-to-distal direction with a suitable liquid under pressure prior to inflating the first balloon.

61. (Previously Presented) A method according to claim 59, wherein the first lumen is purged after inflating the first balloon using a purging liquid under pressure to temporarily deform and unseal the first balloon.

62. (Previously Presented) A method according to claim 59, further comprising:

deflating the first balloon to eliminate the occlusion of the first lumen; and

causing one of ingress and egress flow through the first lumen after the first balloon has been deflated.

63. (Previously Presented) A method according to claim 62, further comprising withdrawing the first balloon along the first lumen after deflating the first balloon and before causing flow through the first lumen.

64. (Previously Presented) A method of sealing a catheter indwelling within a vessel of a patient comprising the acts of:

terminating flow along a hollow interior passageway of the catheter;

after the terminating act, inflating a balloon to seal the hollow interior passageway at a distal end of the catheter to prevent blood in the vessel from entering the hollow interior passageway;

deflating the previously inflated balloon to unseal the hollow interior passageway when flow through the hollow interior passageway of the catheter is desired; and

withdrawing the balloon from the catheter after the deflating act.

65. (Previously Presented) A system for establishing intermittent fluid communication with a patient's bloodstream, comprising:

a catheter including a lumen extending therethrough from a proximal end of the catheter to a distal end thereof, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient; and

a balloon which, when inflated, physically contacts, and seals the distal end of the lumen to prevent blood flow thereinto; and

a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel.

66. (Previously Presented) The system according to Claim 65, wherein the balloon is carried near a distal end of an inflation/deflation stem, the stem extending within the lumen between the proximal and distal ends of the catheter.

67. (Withdrawn) A combination according to Claim 66 wherein the stem carries distance indicia for locating the balloon at the distal end of the catheter tube.

68. (Previously Presented) The system according to Claim 66, wherein a seal is interposed between the catheter and the stem within the lumen at the proximal end of the catheter, the stem being selectively displaceable along the lumen through a central opening in the seal.

69. (Previously Presented) The system according to Claim 65, further comprising a port adjacent the proximal end of the catheter by which a flushing liquid under pressure is selectively displaced proximal-to-distal within the lumen.

70. (Previously Presented) A system for establishing intermittent fluid communication with a patient's bloodstream, comprising:

first and second non-concentric catheters each of the first and second catheters including a lumen extending therethrough between proximal and distal ends thereof, wherein, when in an operative position, the distal ends of the first a and second catheters reside within a blood vessel of a patient;

first and second balloons positionable within distal ends of the first and second catheters, respectively, so that, when inflated, the first and second balloons the respective distal ends of the lumens of the first and second catheters to prevent blood flow thereinto; and

a deflation mechanism for deflating the balloon to reopen the lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel.

71. (Previously Presented) The system according to Claim 70, further comprising a first inflation/deflation stem extending within the lumen of the first catheter and a second inflation/deflation stem extending within the lumen of the second catheter, wherein each of the first and second stems extends for substantially the full length of the first and second catheters, respectively and wherein the first and second balloons are carried near distal ends the first and second stems, respectively.

72. (Previously Presented) The system according to Claim 71, wherein a contiguous seal is interposed between proximal ends of the first and second catheters and the first

and second stems, respectively, within the lumen of the respective one of the first and second catheter, each of the first and second stems being selectively displaceable along the lumen of the respective one of the first and second catheters through a central opening in the corresponding seal.

73. (Withdrawn) A combination according to Claim 72 further comprising a pathway along each catheter tube by which fluid under pressure is delivered to the associated balloon to selectively inflate and deflate the associated balloon.

74. (Previously Presented) The system according to Claim 70, further comprising a port near the proximal end of each catheter by which a flushing liquid under pressure is selectively displaced proximal-to-distal within the corresponding lumen.

75. (Previously Presented) A method according to claim 59, wherein the catheter includes a second lumen, further comprising:

advancing a second deflated balloon along the second lumen to a position at least partially radially within a distal end thereof;

inflating the second balloon to seal the second lumen at the distal end thereof to prevent fluid from entering the distal end of the second lumen; and

prior to inflating the second balloon, purging the second lumen.

76. (Previously Presented) A method according to claim 75, wherein the second

lumen is purged in a proximal-to-distal direction with a suitable liquid under pressure prior to inflating the second balloon.

77. (Previously Presented) A method according to claim 75, wherein the second lumen is purged after the second balloon has been inflated using a purging liquid under pressure to temporarily deform and unseal the second balloon.

78. (Previously Presented) A method according to claim 75, further comprising:

deflating the second balloon to eliminate the occlusion of the second lumen; and

causing one of ingress and egress flow through the second lumen after the second balloon has been deflated.

79. (Previously Presented) A method according to claim 78, further comprising withdrawing the second balloon along the second lumen after deflating the second balloon and before causing flow through the second lumen.

80. (Previously Presented) A method of treating a bodily fluid, comprising the steps of:

inserting a distal end of a catheter into a body lumen including the bodily fluid;

establishing fluid communication with the body lumen via a first lumen of the catheter to initiate a first treatment session to treat the bodily fluid;

sealing the first lumen to discontinue fluid communication with the bodily fluid by:

advancing a first deflated balloon along the first lumen to a position at least partially radially within a distal end thereof; and

inflating the first balloon to seal the first lumen at the distal end thereof; and

reestablishing fluid communication with the bodily fluid by deflating the first balloon to initiate a second treatment session.

81. (Previously Presented) The system according to claim 56, further comprising a second sealing balloon positionable within a distal end of the second lumen, so that, when inflated, the second balloon seals the distal end of the second lumen to prevent blood flow thereinto, wherein the deflation mechanism deflates the second balloon to reopen the second lumen to blood flow thereinto while the distal end of the catheter remains within the blood vessel.

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## EVIDENCE APPENDIX

No evidence has been submitted herewith or is relied upon in the present appeal.

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## RELATED PROCEEDINGS APPENDIX

An Appeal Brief was filed in relation to the present application was filed on August 22, 2006. Prosecution in the present application was subsequently reopened and a Non-Final Office Action issued on March 9, 2007.